

Testing the Addition of Chemotherapy or Chemo-immunotherapy to the Usual Surgery for Advanced Head and Neck Cancer

NRG
ONCOLOGY

Advancing Research. Improving Lives.™



Visit the patient
webpage for this study:



ABOUT THE TRIAL

NRG-HN015 is a clinical study comparing the usual treatment of surgery alone, to using chemotherapy (cisplatin and paclitaxel) or chemo-immunotherapy [carboplatin and paclitaxel with cemiplimab (REGN2810)] plus the usual treatment for people with advanced head and neck cancer. The addition of chemotherapy or chemo-immunotherapy to the usual treatment could shrink your cancer or prevent it from returning. But, it could also cause side effects, which are described in the risks section below.

This study will help the study doctors find out if this different approach is better, the same, or worse than the usual approach. To decide if it is better, the study doctors will be looking to see if the addition of chemotherapy or chemo-immunotherapy before surgery will increase the number of patients that are alive and cancer-free after 2 years from 40 out of 100 with surgery alone, to 56 out of 100 with the study approach.

ABOUT NRG ONCOLOGY

As one of the five research groups in the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN), NRG Oncology carries out clinical trials on sex-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types. NRG Oncology's extensive research organization includes investigators, medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians. The NRG Oncology includes more than 1,300 research sites worldwide, primarily in the United States and Canada. NRG Oncology is a non-profit research organization, funded mainly through grants from the NCI. To contact NRG Oncology, call 267-519-6630 or email info@nrgoncology.org

Frequently Asked Questions

What is a clinical trial?

Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

Who can join this study?

People who have advanced head and neck cancer.

Am I required to be in this study?

No. Taking part in this study is voluntary. You are free to choose to participate or not to participate. If you choose to participate in this study, you are able to leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

What are the possible treatments?

If you decide to take part in this study you will get one of three potential treatments:

- Surgery, **OR**
- Chemotherapy (carboplatin and paclitaxel) for 2 cycles for a duration of 6 weeks, followed by surgery, **OR**
- Chemo-immunotherapy [carboplatin and paclitaxel with cemiplimab (REGN2810)] for 2 cycles for a duration of 6 weeks, followed by surgery.

Depending on the tumor tissue results from the surgery, you may also get radiation therapy plus cisplatin chemotherapy after your surgery.

How long will I be in this study?

After you finish treatment, your doctor will continue to follow your condition and watch you for side effects. They will check you every 3 months for 2 years after treatment. After that, they will check you every 6 months for 2 years and then annually. This means you will keep seeing your doctor annually after treatment.

Are there side effects?

There may be some. Some of the most common side effects that the study doctors know about are: reddening, tanning, or peeling of the skin, milk pain, hair loss, bruising or bleeding, tiredness, anemia, nausea, diarrhea, vomiting, or infection. There may be some risks that the study doctors do not yet know about. Your doctor will review all of the potential side effects with you.

MORE INFORMATION

Visit the National Cancer Institute website at <https://www.cancer.gov> for more information about studies or general information about cancer.

You may also call: 1-(800)-4-CANCER (1-800-422-6237).